

## II. REMARKS

### Preliminary Remarks

Reconsideration and allowance of the present application based on the following remarks and foregoing amendment are respectfully requested. Claims 20, 21, and 24-39 are pending and remain at issue in this application. The applicants respectfully request entry of the amended claims as these amendments place the application in condition for allowance or in the alternative place the application in a better form for appeal.

Amended claim 20 is directed to a recombinant *Corynebacterium glutamicum* bacterium comprising at least one isolated *Corynebacterium glutamicum* polynucleotide selected from the group consisting of (a) an isolated polynucleotide encoding a polypeptide consisting of an amino acid sequence that is at least 90% identical to the amino acid sequence of SEQ ID NO:3, wherein said polypeptide enhances amylase secretion; and (b) an isolated polynucleotide encoding a polypeptide consisting of an amino acid sequence that is at least 90% identical to the amino acid sequence of SEQ ID NO:4, wherein said polypeptide enhances amylase secretion. Amended claim 21 is directed to a recombinant *Corynebacterium glutamicum* bacterium comprising at least one isolated *Corynebacterium glutamicum* polynucleotide selected from the group consisting of (a) an isolated polynucleotide encoding a polypeptide consisting essentially of the amino acid sequence of SEQ ID NO:3, wherein said polypeptide enhances amylase secretion; and (b) an isolated polynucleotide encoding a polypeptide consisting essentially of the amino acid sequence of SEQ ID NO:4, wherein said polypeptide enhances amylase secretion. Support for the phrase "enhances amylase secretion" can be found throughout the specification, for example, on page 12, lines 19-28 and page 23, line 26-28.

Claims 25, 26, 28 and 29 have been amended to be directed to their respective host cells comprising an isolated polynucleotide encoding a particular polypeptide enhances excretion of an amylase from the cytoplasm of said bacterium to a broth. Support for the phrase "enhances excretion of an amylase from the cytoplasm of said bacterium to a broth" can be found throughout the specification as originally filed (e.g., Example 6 and Example 8).

The applicants do not intend by these or any amendments to abandon subject matter of the claims as originally filed or later presented, and reserve the right to pursue such subject matter in continuing applications.

## **Patentability Remarks**

### **Rejection Pursuant to 35 U.S.C. §101, Non-Statutory Subject Matter**

In paragraph 3 of the official action, the examiner rejected claims 20-39 under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter. Specifically, claims 20-39 as written [at the time of mailing this office action], do not sufficiently distinguish over nucleic acids, proteins, cells or antibodies as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. The examiner recommends the claims should be amended to indicate the hand of the inventor, e.g., by insertion of “transformed *Corynebacterium glutamicum*.”

In view of the foregoing amendments, the applicants submit that amended claims 20-39 now indicate the hand of the inventor by insertion of the phrase “recombinant *Corynebacterium glutamicum*.”<sup>1</sup> Support for this amendment is found throughout the application as originally filed. Claims 22 and 23 have been cancelled without prejudice. Accordingly, the applicants submit that the rejection of claims 20, 21, 24-38 pursuant to 35 U.S.C. § 101 for claiming non-statutory subject matter is overcome and request withdrawal of the rejection.

### **Rejection Pursuant to 35 U.S.C. §112, First Paragraph, Written Description**

In paragraph 5 of the official action, the examiner rejected claims 20-23, 25, 26, and 28-39 under 35 U.S.C. § 112, first paragraph, for allegedly lacking adequate written description. Specifically, the examiner alleged that the recitation of the phrase “wherein said polypeptide has at least the same activity in promoting excretion of an amylase of *Streptomyces griseus* from the cytoplasm of said bacterium to a broth” in claims 20-23 has no support in the specification or claims as originally filed. In addition, the examiner alleged that the recitation of the phrase “has at least the activity of promoting excretion of an amylase

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<sup>1</sup> The examiner is reminded of the telephone conversation with the undersigned during the week of August 29, 2003, wherein the examiner gave tentative approval for use of the terminology “recombinant” (*i.e.*, pending further approval).

from the cytoplasm of said bacterium to a broth” in claims 25, 26, 28, and 29 has no support in the specification or claims as originally filed.

In view of the foregoing amendments, these rejections are now moot. Specifically, and solely for the purpose of expediting prosecution, and without prejudice to the applicant's right to seek broader claims in a continuing application, the applicants have removed the language referred to by the examiner from claims 20, 21, 25, 26, 28, and 29 and cancelled claims 22 and 23 without prejudice.

Support for the phrases “enhances amylase secretion” and “enhances excretion of an amylase from the cytoplasm of said bacterium to a broth” can be found throughout the specification as originally filed. For example, the specification teaches plasmids that enhance expression of the *secD* (polynucleotide sequence-SEQ ID NO: 1; amino acid sequence SEQ ID NO: 3) and *secF* (polynucleotide sequence-SEQ ID NO: 1; amino acid sequence SEQ ID NO: 4) genes enhance the secretion of the heterologously expressed amylase protein in *Corynebacterium glutamicum* (page 23, line 12 to page 14, line 28). Specifically, Example 5 teaches construction of the heterologous amylase expression vector pIAmy2. Example 6 teaches how the amylase activity assays were performed measuring amylase secretion from the cytoplasm of *C. glutamicum* to the broth. Example 7 teaches that *secD* and *secF* encode transport proteins that are inevitable for the export of the heterologous amylase. Example 7 further teaches that the pSecDF expression vector harboring the *secD* and *secF* genes into *C. glutamicum* strain that also contained the amylase expression vector pIAmy2. Example 8 teaches the overexpression of *secD* and *secF* enhances the amylase secretion 1.5 fold in *Corynebacterium glutamicum* (page 23, lines 26 and 27). When the *secD* and *secF* genes are combined with *sec* genes *secE* and *secY* the amylase secretion increases 2 to 3 fold in *C. glutamicum*. These experiments were also performed on solid medium and the growth on starch was found to be directly proportional to the amylase secretion which was proportional to the expression level of the *sec* genes (page 24). The applicants submit these examples convey to one skilled in the art that the inventors, at the time the applicant was filed, has possession of the claimed invention, specifically the biological activities of “enhance[d] excretion of amylase” and “enhance[d] excretion of an amylase from the cytoplasm of said bacterium to a broth.”

In view of the foregoing amendments and remarks, the applicants submit that the rejection of claims 20, 21, 25, 26, 28-39 pursuant to 35 U.S.C. § 112, first paragraph, for lack


of written description, is now moot and therefore respectfully request withdrawal of the rejection.

### III. CONCLUSION

In view of the foregoing, the claims are now believed to be in form for allowance, and such action is hereby solicited. If any point remains in issue which the Examiner feels may be best resolved through a personal or telephone interview, please contact the undersigned at the telephone number listed below.

Respectfully submitted,

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